

PHARMATON
NATURAL HEALTH PRODUCTS

Thomas W. Peterson
VICE PRESIDENT, GENERAL MANAGER

September 10, 1996

VIA HAND DELIVERY

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pharmaton Natural Health Products, Division of Boehringer Ingelheim Pharmaceuticals, Inc., wishes to notify the Food and Drug Administration that within the past 30 days the company has begun marketing a dietary supplement with a label which bears statements of nutritional support.

The dietary supplement for which the statements are made is PROSTATONIN® softgel capsules, which consist principally of Standardized Pygeum africanum extract PY102 and Standardized Urtica dioica extract UR102. The statements of nutritional support read as follows:

"Dietary Supplement for Prostate Health"

"Combination supplement aimed at promoting prostate health"

A copy of the package for the product is attached.

These statements are accompanied by the required disclaimer indicating that the statements have not been evaluated by FDA and that the product is not intended to diagnose, treat, cure, or prevent any disease. (The disclaimer is in bold print in a box.) The Company possesses adequate substantiation for these statements of nutritional support which renders the statements truthful and non-misleading, and thus permissible under the DSHEA.

Sincerely,



Thomas W. Peterson

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